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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/829,511 | 04/22/2004 | Rangarajan Sundar | P1070 US | 7340 |

7590 06/22/2010

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| EXAMINER | |
|---|---|
| DOWE, KATHERINE MARIE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3734 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 06/22/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/829,511 | SUNDAR, RANGARAJAN | |
| | Examiner | Art Unit | |
| | KATHERINE M. DOWE | 3734 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4-7,9-28,30 and 32-37* is/are pending in the application.

4a) Of the above claim(s) *11-28,30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9,10 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 24, 2010 has been entered.

2. Claims 1, 2, 4-7, 9-28, 30, and 32-36 are currently pending, with claims 11-28, 30, and 32 withdrawn from consideration.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2 and 7 each recite "the polymer coating includes a therapeutic agent". However dependent claims 1 and 6 each recite "the coating being a non-biologically active polymer". There is insufficient support in the disclosure for a polymer coating including a therapeutic agent, wherein that polymer coating is non-biologically active.

5. Claims 2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 2 and 7 each recite "the polymer coating includes a therapeutic agent". However dependent claims 1 and 6 each recite "the coating being a non-biologically active polymer". The specification does not enable one of skill in the art to make a polymer coating containing a therapeutic agent to be non-biologically active. It is generally held in the art that a "therapeutic agent" is a drug, natural hormone, or other substance that is "biologically active".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 7 each recite "the polymer coating includes a therapeutic agent". However dependent claims 1 and 6 each recite "the coating being a non-biologically active polymer". It is unclear how a polymer coating including a therapeutic agent can be non-biologically active.

***Double Patenting***

8. Claims 1, 2, 4-7, 9, 10, and 33-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/827,817. In the copending application, claim 3 is dependent on claim 1. For double patenting to exist as between the rejected claims and copending application claim 3, it must be determined that the rejected claims are not patentably distinct from claim 3. In order to make this determination, it first must be determined whether there are any

differences between the rejected claims and claim 3 and, if so, whether those differences render the claims patentably distinct.

Claims 1, 2, 4-7, 9, 10, and 33-37 recite a "catheter" (see line 2 of claim 1 of the copending application as amended July 20, 2009), a balloon operably attached to the catheter" (see line 3 of claim 1 of the copending application), "a stent disposed on the balloon" (see line 4 of claim 1 of the patent), "a silane layer" (see lines 8-9 of claim 1 of the copending application), and "a coating disposed on the silane layer" (see lines 6-7 of claim 1 of the copending application) including "a therapeutic agent" (see lines 1-2 of claim 3 of the copending application) and a "polymer" (see line 10 of claim 1 of the copending application)

It is clear that all the elements of claims 1, 2, 4-7, 9, 10, and 33-37 are to be found in claim 3 (as it encompasses claim 1). The difference between claims 1, 2, 4-7, 9, 10, and 33-37 of the application and claim 3 of the copending application lies in the fact that the copending application claim includes many more elements and is thus much more specific. Thus the invention of claim 3 is in effect a "species" of the "generic" invention of claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 2, 4-7, 9, 10, and 33-37 are anticipated by claim 3 of the copending application, it is not patentably distinct from claim 3.

9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1, 2, 4-7, 9, 10 33, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,356,433) in view of Yan (US 6,240,616). Regarding claims 1, 4-6, 9, 10 33, 36, and 37, Rowland discloses the invention substantially as claimed including a stent disposed on a balloon catheter (col 2, ll 64-68). The stent comprises a stainless steel frame (col 4, ll 35-39) and an amino silane layer disposed on the stent for binding biologically active agents (col 4, ll 40-62). However, Rowland does not disclose a coating disposed on the silane layer, wherein the coating is a non-biologically active polymer including polycaprolactone (PCL). Yan discloses a stent and teaches a coating (100) may be applied to the external surface, wherein the coating is a non-biologically active polymer including polycaprolactone (PCL). Yan teaches the polymer coating "is bioabsorbable, but no therapeutic agent is loaded into the polymer. The coating 100 dissolves after implantation and this delays the time that a therapeutic agent is released into the vasculature of the patient." (col 9, ll 22-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rowland such that a non-biologically active polymer layer including PCL was disposed over the silane layer to control the release rate of the biologically active agents attached to the amino-silane layer.

Regarding claims 2 and 7, Yan further teaches that while a biologically active agent may be loaded directly onto the stent (analogous to biologically active agents bound to the amino silane layer in Rowland), the application of a coating comprising an additional therapeutic agent can increase the dosage of the therapeutic agent to the target site or a second different therapeutic agent can be delivered through the polymeric coating. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an additional polymeric layer that comprises a therapeutic agent to the device of Rowland to improve the drug delivery capability of the stent.

12. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,356,433) and Yan (US 6,240,616), as applied to claims 1 and 6 above, further in view of Sagiv (US 4,539,061). Rowland discloses the invention substantially as claimed as shown above. However, Rowland does not disclose the thickness of the silane layer. Sagiv discloses a similar system comprising a substrate layer (col 3, ll 26-33; analogous to the stent of Rowland), an intermediate silane layer (col 4, ll 13-15), and biologically active compound coupled to the surface of the intermediate layer (col 6, ll 45-47). The intermediate layer is formed as a monolayer with individual monolayers formed on top of one another on the surface of the substrate (col 2, ll 43-57; col 8, ll 7-9; col 11, ll 30-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rowland such that the silane layer comprised multiple monolayers as taught by Sagiv to ensure the entire stent, or substrate, comprised the polymer coating which is applied over the silane layer. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Rowland and Sagiv such that the silane layer comprised 8 to 10 monolayers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Alternatively, it would have been prima facie obvious to try modifying the silane layer of Rowland such that the thickness of the silane layer was 8-10 monolayers in an attempt to provide an improved coated stent as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

***Response to Arguments***

13. Applicant's arguments, see amendment, filed April 26, 2010, with respect to the rejection(s) of claim(s) 1, 2, 4-7, 9, 10, and 33-36 under Rowland (US 5,356,433) have been fully considered and are persuasive. Applicant argues Rowland does not disclose a coating disposed on the silane layer, wherein the coating is a non-biologically active polymer. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yan (US 6,240,616).

14. Applicant's arguments regarding claims 34 and 35 and the teaching of Sagiv (US 4,539,061) have been fully considered but they are not persuasive. Applicant argues Sagiv discloses a multilayer silane layer of up to four monolayers, and thus the 8-10 monolayers of Applicant's invention is a surprising and unexpected result. The examiner respectfully disagrees. Applicant acknowledges Sagiv clearly teaches a multilayer silane layer. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. The examiner notes, Applicant has provided no evidence to establish an unobvious difference between the claimed product and the prior art, but rather has merely argued such alleged difference. Mere arguments can not take the place of evidence. *In re Walters*, 168 F.2d 79,80, 77 USPQ 609,610 (CCPA 1948); *In re Cole*, 326 F.2d. 769,773, 140 USPQ 230,233 (CCPA 1964); *In re Schulze*, 346 F.2d 600,602, 145 USPQ 716,718 (CCPA 1965); *In re Lindner*, 457 F.2d 506,508, 173 USPQ 356,358 (CCPA 1972); *In re Pearson*, 494 F.2d 1399,1405, 181 USPQ 641,646 (CCPA 1974); *Meitzner v. Mindick*, 549 F.2d 775,782, 193 USPQ 17,22 (CCPA), cert. Denied, 434 U.S. 854 (1977); *In re DeBlauwe*, 736 F.2d 699,705, 222 USPQ 191,196 (Fed. Cir. 1984).

***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
June 18, 2010

/K. M. D./
Examiner, Art Unit 3734

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/21/10